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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,046	04/01/2005	Yukiko Yokoi	2005_0520A	7940

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,046	YOKOI ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 31-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/20/09 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 03/20/09. Claims 1-26 and 31-40 are pending in the applications, with claims 27-30 having being cancelled. Accordingly, claims 1-26 and 31-40 are being examined on the merits herein.

Receipt of the aforementioned amended claims and amended specification is acknowledged and such amendments have been entered. The Examiner further acknowledges receipt of the Declaration of Nobutaka Yokota which states on the record the mistranslation of certain words of the instant application.

Applicant's arguments against the rejection of claims 2, 5, and 9-11 under 35 U.S.C. § 112 second paragraph has been fully considered. Given that applicant has provided evidence as to what is known in the prior art regarding dosage equivalence of

100 mg efficacy of cefditoren pivoxil, such arguments are found persuasive. Consequently, the rejection under 35 U.S.C. § 112, second paragraph is hereby withdrawn.

Applicant's arguments against the rejection of claims 1-26 and 31-38 under 35 U.S.C. § 103(a) has been fully considered. Applicant argues that Shimizu teaches a sucrose fatty acid ester as a lubricant among a laundry list of lubricants and a laundry list of active ingredients with no motivation to select and combine a sucrose fatty acid ester and cefditoren pivoxil. Applicant further argues that no motivation was provided as to why one of ordinary skill in the art would select those particular combinations. The Examiner however contends that Shimizu does teach addition of a pharmacologically active ingredient such as the antibiotic cefditoren pivoxil along with addition of a sugar. Moreover, Shimizu teaches addition of binders such as hydroxypropylmethylcellulose and lubricants including sucrose fatty acid ester. Consequently, the Examiner contends that such composition does indeed render obvious applicant's invention. While Shimizu may have listed various types of active ingredients and lubricants, such disclosure nonetheless allows one of ordinary skill in the art to envisage potential actives and lubricants that can be added to said composition with a reasonable expectation of success. Onodera, on the other hand, was provided to demonstrate that amorphous cefditoren pivoxil is more suitable for oral formulations as it provides higher thermal and storage stability. As for applicant's arguments to newly added claims 39 and 40, such arguments are moot since such claims are yet to be examined. Thus, in view of

applicant's amendment of the claims, the rejection of claims 1-26 and 31-38 under 35 U.S.C. § 103(a) is hereby withdrawn.

For the foregoing reasons, the rejections of record are hereby withdrawn. However, in view of applicant's amendment, the following 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta et al. (WO00/06126) in view of Nakamura (U.S. 2002/0015730 A1).

WO 2002/087588 A1 is the PCT counterpart to U.S. 2004/0115272 A1. WO 2002/087588 A1 is prior art under U.S.C. 102 (a) as a result of its July 11, 2002 publication date. Because WO 2002/087588 A1 and U.S. 2004/0115272 A1 appear to have identical disclosures, the U.S. patent application is being used as a translation of WO 2002/087588 A1 PCT. While any reference hereinafter to column and line numbers

will be based upon the U.S. patent application disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Ohta teaches an amorphous cefditoren pivoxil composition possessing excellent stability and dissolvability and which results in a production process of the amorphous composition (see abstract, pg. 1, paragraphs 0002 and 0014-0015 and pg. 2, paragraph 0020). Particularly, Ohta teaches that the amorphous cefditoren pivoxil composition according to the present invention comprises cefditoren pivoxil and a pharmaceutically acceptable organic polymeric compound, wherein the composition is obtainable by grinding a crystalline cefditoren pivoxil in the presence of a pharmaceutically acceptable organic polymeric compound to convert the crystalline cefditoren pivoxil to an amorphous substance (see abstract and pg. 2, paragraph 0017). By pharmaceutically acceptable organic polymeric compound, Ohta teaches that preferred compounds include hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose, povidone or a mixture thereof (instant claims 3-4, 7-8; see pg. 2, paragraphs 0032-0033). As for the dosage form suitable for oral administration, Ohta teaches that such dosages are not particularly limited and may be selected from various forms depending on the use and can include powders, granules, pills, capsules, and tablets (pg. 3, paragraph 0046). Additionally, Ohta teaches addition of pharmaceutically acceptable carriers including excipients, binders such as hydroxypropylcellulose, hydroxypropylmethylcellulose, and povidone; disintegrants, and colorants (instant

claims 6 and 12-19; see pg. 3, paragraphs 0047 and 0049). Appropriate doses of cefditoren pivoxil is dependent upon various factors but can typically be used at a range of 25 to 2000 mg/kg (see pg. 4, paragraph 0054). Particularly, Ohta teaches amorphous composition 5 where cefditoren pivoxil and hydroxypropylmethylcellulose are in a 50/50 ratio (see pg. 4, paragraph 0063-0064 and table 1). Importantly, Ohta teaches preparation 3 which contains amorphous composition 5 (i.e. including cefditoren pivoxil), hydroxypropylcellulose, and sucrose fatty acid ester mixed together to prepare a powder (instant claim 1; see pg. 6, paragraphs 0087 and 0096-0097).

Ohta does not teach a weight ratio of the sucrose fatty acid ester to the cefditoren pivoxil in a range of 0.008 to 0.816. Similarly, Ohta does not teach that crystallization of the amorphous cefditoren pivoxil is inhibited.

While the exact ratio of the sucrose fatty acid ester is not disclosed by Ohta, the Examiner contends that it is well within the purview of the skill of the artisan at the time of the invention to adjust the concentration and range of the sucrose fatty acid ester of the composition during the course of routine experimentation so as to obtain the desirable type of properties (i.e. solubility) in the composition or if such preparation is being made on a smaller scale.

Nakamura teaches that sucrose fatty acid ester (SE) has eight hydroxyl groups in the hydrophilic group and so it is possible to manufacture SE ranging from low HLB to high HLB by controlling the degree of esterification (see pg. 1). Nakamura additionally

teaches that SE possesses solubilizing properties and can inhibit crystal growth (see pg. 1).

Thus, to one of ordinary skill in the art would have found it obvious to vary the ratio of the sucrose fatty acid ester depending on the scale of the preparation. Moreover, one of ordinary skill in the art would have found it obvious to add SE and vary such concentration for the purpose of inhibiting crystals or solubility purposes. Consequently, one of ordinary skill in the art would have been motivated to add SE and vary its concentration in view of the disclosure of Nakamura with the reasonable expectation of providing a composition that possesses high stability and high dissolvability.

Claims 20-26 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta et al. (WO00/06126) in view of Nakamura (U.S. 2002/0015730 A1) as applied to claims 1-19 and in further view of Hoffmann et al. (U.S. 2002/0015730 A1, previously cited).

The Ohta and Nakamura references are as discussed above and incorporated by reference herein. Ohta and Nakamura however do not teach the sucrose fatty acid ester with an HLB value of 11 to 20. Similarly, Ohta does not teach that the amorphous cefditoren pivoxil is at the core while the sucrose fatty acid ester is present in an exterior portion of said particles. Finally, Ohta and Nakamura do not teach that the composition

has an amorphousness-retaining character of the amorphous cefditoren pivoxil in aqueous medium for at least one day.

Given that the goal of the invention was to obtain an amorphous cefditoren pivoxil composition, the examiner contends that the composition of Ohta thus necessarily retains its amorphous character in aqueous medium for at least one day. Furthermore, given that these characteristics are obtained as a result of mixing the pharmaceutically active ingredient with a sugar fatty acid ester, the Examiner concludes that the composition of Ohta necessarily maintains its amorphous character. If however applicant disagrees, it is incumbent upon applicant to demonstrate through comparative results that the composition of Ohta does not maintain its amorphous character.

Moreover, in light of the disclosure of Nakamura that the HLB of SE can vary by controlling the degree of esterification, the Examiner contends that one of ordinary skill in the art through routine optimization can vary the esterification of SE depending on the desired HLB for the SE (instant claims 21-22, 31, and 35).

Hoffmann et al. teach oral pharmaceutical formulation with variably adjustable release rate which comprises one or more active ingredients and one or more sucrose ester of a fatty acid as the sole release-controlling agent (see abstract and pg. 3, paragraph 0040). Hoffman et al. also teach the formulation in the form of a tablet wherein the sucrose esters of fatty acid are used in the range of 1-95% and are able to

control the release of the active ingredients (see pg. 3, paragraphs 0042-0043, pg. 4, paragraphs 0059-0060). Importantly, Hoffman et al. teach the use of sucrose esters with a low HLB value from about 1 to about 16 (instant claims 21-22, 31, and 35; see pg. 3, paragraph 0044-0045). Particularly, Hoffman et al. teach that the granules or pellets of the invention which may or may not contain sucrose esters of fatty acids in the granulate can be coated instead with sucrose fatty acid esters (instant claim 20; see pgs. 4-5, paragraphs 0061 and 0073).

It would have been obvious at the time of applicant's invention to one of ordinary skill in the art to coat the amorphous composition 5 of Ohta with sucrose fatty acid esters since Hoffman et al. teach the use of such sucrose fatty acid esters as controlled release agents with the reasonable expectation of providing a composition that is effective in releasing cefditoren pivoxil at particular site and appropriate time.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

07/01/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617